APR 30 1997

K970448

510(k) SUMMARY

(1)	Submitter:	Tecnol Medical Products, Inc. 7201 Industrial Park Blvd. Fort Worth, TX 76180
	Prepared By:	Ruth L. Jones
	Date Submitted:	March 24, 1997
(2)	Device Name/ Trade Name:	Tecnol PFR95™ Particulate Filter Respirator and Surgical Mask FluidShield® Protection
	Common Name:	Surgical Mask Also sometimes referred to as a particulate respirator.
	Classification Name:	Surgical Apparel, as described in 21 CFR 878.4040
(3)	Predicate Device:	Gerson Isolair APR Type N95 Model 2735 Respirator and Surgical Mask
(4)	Device Description:	Respirator consisting of nonwoven inter facing, filter media(s), a fluid barrier film, and an outer facing. It covers the nose and mouth of the wearer, and is held in place with two synthetic elastic headbands, conforming to the curvature of the wearer's nose with a malleable nosepiece.
(5)	Intended Use:	Meets the CDC guidelines for TB exposure control. Has a filter efficiency level of 95% against solid particulate aerosols free of oil (Type N95 respirator). Designed to be fluid resistant to splash and spatter of blood and body fluids.
(6)	Technological Characteristics Comparison:	No new technological characteristics are used in the PFR95™ mask.

(7) Performance Data:

Filtration Efficiency: Subject device samples met the NIOSH required sodium chloride test with 0.3 micron particles. At no time can the filtration efficiency drop below 95%.

Fluid Resistance: Subject device samples were challenged with 2cc of synthetic blood at a speed simulating release of blood from an artery. No fluid penetration was observed.

Face Fit: Subject device samples were tested using a qualitative fit test.

Ease of Breathing: Subject device samples met the requirements of the NIOSH airflow resistance test which requires initial resistance (inhalation) to be less than 35mm H_2O.

CONCLUSION: The results of these nonclinical tests, when compared with data available and/or claims made on the predicate device, demonstrate that the subject device is as safe and effective as the predicate device, and performs as well as the predicate device.